Amendment to APF25

Good compounding practice chapter

The APF Editorial Board has approved an amendment to APF25 expiry date guidance (APF25, page 53). The amendment is shown in bold below.

“The following guidance applies to expiry dates for non-sterile compounded medicines:

• The expiry date is 28 days or less from the date the medicine is compounded, unless otherwise specified in the APF or in a reliable stability study. An expiry date of less than 28 days may be more appropriate in some clinical circumstances.

• The expiry date of compounded capsules or powders is 6 months or less from the date the medicine is compounded, provided the ingredients are stable in air and not hygroscopic or deliquescent.

• If the expiry date from a reliable stability study that uses the same formulation, packaging and storage conditions as the compounded medicine differs from the expiry date guidance in the APF (longer or shorter), the expiry date from the stability study should be used.

• The expiry date of a compounded medicine must never be longer than 6 months.

• The expiry date of a compounded medicine must not be later than the expiry date of any ingredient.”

The expiry date guidance in APF digital was updated on 10 August 2021.